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Award Number: DAMD17-00-1-0695

TITLE: Telephone-Linked Care: Enhancing Self-Care for Women
with Breast Cancer

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REPORT DATE: September 2002

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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20030319 011

REPORT DOCUMENTATION PAGEForm Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE September 2002	3. REPORT TYPE AND DATES COVERED Annual (1 Sep 01 - 31 Aug 02)	
4. TITLE AND SUBTITLE Telephone-Linked Care: Enhancing Self-Care for Women with Breast Cancer			5. FUNDING NUMBERS DAMD17-00-1-0695	
6. AUTHOR(S) Kathleen H. Mooney, R.N., Ph.D. Susan Beck, R.N., Ph.D. Robert Friedman, M.D. Ramesh Farzanfar, Ph.D.				
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9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited			12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 Words) <p>The objective of this pilot study is to develop informational messages about managing 6 common symptoms (nausea/vomiting, trouble sleeping, fatigue, trouble thinking, fever/chills, and pain), integrating them with a computer-based telephone symptom monitoring system, Telephone Linked Care (TLC) and then evaluating the usefulness of the TLC system and the informational messages during a cycle of chemotherapy for breast cancer. Using an experimental design with random assignment to the TLC program or standard care, participants in the experimental group will call the TLC system daily. Descriptive statistics and t-test will be used for analysis. The specific aims of the study are:</p> <ol style="list-style-type: none">1. To test the feasibility of a computer-based telephone communication system (TLC) to provide informational messages about symptom management self care strategies for breast cancer patients during a cycle of chemotherapy.2. To assess participant satisfaction, level of acceptability and the degree of difficulty in using the informational messages from the patient's perspective.3. To compare the use of self care strategies, their perceived effectiveness and the source of information about the self care strategy between patients utilizing the TLC system and a control group receiving standard care.				
14. SUBJECT TERMS breast cancer, symptoms, self-care, informatics			15. NUMBER OF PAGES 14	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

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INTRODUCTION

Today most cancer treatment is provided on an outpatient basis. While this is both economical and preferable for most cancer patients, it presents logistical difficulties for providing adequate management of the side effects that result from these treatments. Cancer chemotherapy causes a variety of side effects that occur within hours to two or three weeks after treatment. Since patients are at home during this time, they must be the ones to identify and manage them, determining on their own what self-care activities might be helpful in managing problems and determining when they need to contact the clinic for further assistance. Employing emerging telecommunication technology may help monitor side effect patterns and provide a method to coach cancer patients about self care strategies at the time they are experiencing symptoms (Greist, 1997; Friedman, Stollerman, Mahoney, Rozenblyum 1997). Basic screening questions can be asked with patients responding with a numerical response using the touch tone keys on the telephone. If symptoms are present, the computer is programmed to ask further assessment questions. In addition to symptom monitoring, patient education about symptoms, including self care strategies, can be provided and tailored to the patient's specific symptom profile. Once such computer-based telecommunication system is Telephone Linked Care (TLC) that was developed by a medical informatics team led by Robert Friedman, M.D. at Boston Medical Center (Friedman et al., 1997). We are the first group to adapt the TLC technology to the cancer treatment setting (Mooney, Beck, Friedman, Farzanfar, 2002). The current pilot study, funded by this Concept Award, extends our previous work with just the symptom monitoring function of the TLC system to develop and test the symptom self care counseling component of the TLC system for patients receiving chemotherapy for breast cancer.

The objective of this pilot study is to develop informational messages about managing 6 common symptoms (nausea/vomiting, trouble sleeping, fatigue, trouble thinking, fever/chills, and pain), integrating them with the TLC symptom monitoring system and then to evaluate the usefulness of the informational messages for patients receiving a cycle of chemotherapy for breast cancer. The specific aims of the study are:

1. To test the feasibility of a computer-based telephone communication system (TLC) to provide informational messages about symptom management self care strategies for breast cancer patients during a cycle of chemotherapy.
2. To assess participant satisfaction, level of acceptability and the degree of difficulty in using the informational messages from the patient's perspective.
3. To compare the use of self care strategies, their perceived effectiveness and the source of information about the self care strategies between patients utilizing the TLC system and a control group receiving standard care.

BODY

The study has been developed over three phases. During the first year, the initial phase of the study was completed. This involved the development of the informational messages for the 6 symptoms then integrating them into the TLC symptom monitoring script. University of Utah IRB approval was also obtained for the human subjects (phase three) portion of the study. Human protection approval was also submitted to the Department of Defense but final approval was deferred until the final wording of the script was complete which occurs at the end of phase two. A no-cost one year extension was obtained to continue the study.

During this current year the second phase of the study was completed. The self-care messages were converted into the TLC system and the system was extensively tested. Based on the testing,

final changes to the telephone script were made. The process of integrating the self care messages into the TLC system was carefully coordinated between the Utah investigative team and the Boston informatics team. This entailed five steps: creating the design specifications, computer specification of the conversation logic, design of the system's database, entering the dialogue content with professional voice recording of the dialogue and extensive field testing including final revision. Submission of the final script for review of human subjects protection by the Department of Defense was accomplished in July 2002. Another no cost extension was applied for and obtained to complete the final phase of the study.

The human protection approval was finally received in September 2002 and the phase three pilot study was begun. The study has been open to accrual for two weeks with 2 participants on study and an additional 6 in the process of eligibility determination.

KEY RESEARCH ACCOMPLISHMENTS

1. Development of self-care strategies for 6 common symptoms resulting from chemotherapy for breast cancer
2. Development of an operational computer-based telephone system, Telephone-Linked Care, that monitors and provides feedback on self-care strategies for chemotherapy related symptoms during breast cancer treatment.

REPORTABLE OUTCOMES

None to date.

CONCLUSIONS

The study is progressing and is now in the final phase where it is being tested by women with breast cancer. We anticipate data collection to be completed in the next 10 months. We will then analyze the data and provide the final report in August 2003.

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Mooney, K.H.; Beck, S.L.; Friedman, R.H.; Farzanfar, R. (2002) Telephone-linked care for cancer symptom monitoring: a pilot study. *Cancer Practice* 10(3): 147-154.

APPENDICES

Copy of Mooney, K.H.; Beck, S.L.; Friedman, R.H.; Farzanfar, R. (2002) Telephone-linked care for cancer symptom monitoring: a pilot study. *Cancer Practice* 10(3): 147-154.

cancer-care providers about patients' at-home symptom status could lead to improved symptom control thus enhancing cancer care. This report summarizes a pilot study that evaluates such a system using telecommunications technology. The purpose of the study was to explore the feasibility of using the computerized system to generate symptom alert notification to the oncologist for patients who experienced poorly controlled symptoms during chemotherapy.

Impact of Poorly Controlled Symptoms

Chemotherapy-related symptoms disrupt normal daily living activities and diminish quality of life.^{5,6} If they are working, patients usually take time off from work or plan leaves of absence. Otherwise, they schedule treatment for the end of the week so that they can deal with the initial treatment-related symptoms over the weekend. When symptoms are poorly controlled, even household tasks and normal self-care functions are disrupted. Patients may spend all but a few hours of their day in bed trying to cope with side effects. Besides physical symptoms, several studies have shown that almost half of chemotherapy patients report elevated levels of anxiety and depressed mood.⁷⁻¹⁰ Patients dread the chemotherapy-related symptom experience and as many as a quarter of patients receiving chemotherapy may consider stopping treatment.¹¹

While patients are usually given instructions during their clinic visits about potential symptoms and self-care management strategies to cope with them, these instructions often are not tailored to the patient's specific symptom experience, are forgotten by the patient, or are ineffective.¹² Thus, many patients are unsuccessful in adequately monitoring their symptom experience, are unable to carry out side-effect management instructions, and do not seek effective follow-up care. Community services, such as a visiting home health nurse, are generally not available or reimbursable for home cancer management after chemotherapy administration.

While the ambulatory administration of cancer chemotherapy is both economical and preferable for most patients, it presents challenges to providing adequate monitoring of symptoms from treatment-related side effects that the patient will experience at home in the interim between scheduled clinic appointments.¹² Many of these symptoms remain poorly controlled even though there have been advances in knowledge about how to manage them. Many patients do not know when to call to report symptoms, are reluctant to "bother" their provider, or wait until symptoms are seriously unmanageable to ask for help. As a result, their providers have no way of knowing that symptoms are out of control, and therefore they cannot intervene. The patients on the other hand, have no recourse but to bear the consequences of uncontrolled symptoms or to phone the clinic and seek further assistance. Even when they successfully contact their clinic, providers may find it difficult to respond immediately to the call or may not have time to assess systematically the full range of symptoms. In fact, the

most common time that symptoms are fully assessed is at the time of the next scheduled clinic appointment, which is usually when the patient has recovered from the previous cycle of chemotherapy and is experiencing the fewest symptoms.

Unfortunately, effective and innovative symptom management services for oncology patients that can be offered at home are lacking. The literature contains numerous articles about telephone triage in the ambulatory oncology clinic.¹³⁻²⁰ However, none identifies what portion of symptomatic patients receiving chemotherapy use the telephone triage service or reports their satisfaction in achieving improved symptom relief. Subspecialty services from supportive-care and palliative-care clinics are increasing, especially in cancer centers, but, as referral programs, they do not automatically include all patients receiving chemotherapy. In addition, they usually operate in a traditional manner, requiring patients to come to the clinic for assessment. There is an obvious need for effective and efficient methods to monitor the chemotherapy-related side effects of patients with cancer at home and, thus, to facilitate oncology providers' timely intervention. This could lead to improved symptom relief, better tolerance of the rigors of chemotherapy, and improved quality of life.

Telephone-Linked Care Technology

The application of information technology to the management of patient care is at an early stage. Until recently, such work has used stand-alone desktop computers in patient homes without any network connections. Nowadays, patients can be connected to their providers either via computer networks²¹⁻²³ or simply by using their touch-tone telephones. Indeed, computer-based systems that employ interactive telecommunications technology, particularly those using computer-controlled telephony known as interactive voice response technology, have a great potential for a revolutionary impact on healthcare delivery by expanding accessibility and reducing costs.²⁴⁻³⁷ Systems that are based on interactive voice response technology are widely accessible to and familiar to the general patient population and can be easily used for chronic disease monitoring and alerting.

Telephone-linked care (TLC) is a computer-based telecommunications system that was developed by the Medical Information Systems Unit at Boston Medical Center (Boston University) to help clinicians care for patients with chronic health conditions. Besides its application to cancer risk reduction, previous applications of TLC have been developed for hypertension, congenital heart disease, diabetes, chronic obstructive pulmonary disease, asthma, and hypercholesterolemia as well as for monitoring the functional status of disabled individuals.^{24,26}

TLC carries out automated telephone conversations with patients by using computer-controlled digitized human speech. The patients, in turn, "speak" to TLC by pressing the keys on their telephone keypad or by speaking into the telephone receiver. These conversations are designed

be eligible, patients needed to have daily access to a touch-tone telephone, understand and speak English, and have no physical or mental conditions that would have prevented them from participating. A total of 27 patient participants were enrolled. The participants were under the care of two medical oncologists.

Procedure

Institutional review board (for human participants) approval was obtained before implementing the study. Potential patient participants were contacted to determine their interest in the study before or during a clinic visit that occurred before they commenced a cycle of chemotherapy. A research assistant met with potential participants during their clinic visit, evaluated them for eligibility, invited them to participate, and obtained written informed consent. After signing the consent, each participant received a personal identification number and was instructed on how to use TLC Chemo-Alert. Participants were instructed to call the TLC-Chemo-Alert daily, beginning 24 hours after chemotherapy administration of the current cycle and continuing until it was time to begin another cycle of chemotherapy. Because of the pilot nature of the study, no back-up calling function was put in place to call participants if they failed to call into TLC on any particular day. A toll-free telephone help line was available for participants to call to report any difficulty with using TLC.

The participants also were told at the beginning of the study and on each subsequent phone call to call their physician or the clinic if they were experiencing symptoms that concerned them. Although alerts were sent to providers, participants were not aware that these alerts were being sent. Because the pilot study was limited in scope, the researchers did not want participants to believe that TLC was providing a substitute for their own need to notify their physician to seek symptom care. Thus, for example, patients had been instructed by their providers to call them immediately if they experienced a fever greater than 100.5°F. At the end of the chemotherapy cycle, the participants were interviewed by the research assistant over the telephone to evaluate their opinions about TLC-Chemo Alert and to obtain suggestions for further improvement of its application. While alerts were sent to a patient's physician, researchers did not track what the physician did with the information. For this pilot study, the interest was in testing the feasibility of the TLC system for patient use and the reliability of the TLC system, not the provider's action. Currently, the authors are conducting a larger study of TLC-Chemo Alert that follows provider response to alerts and subsequent participant symptom profiles.

Results

Sample Description

Of the 27 participants enrolled, 69% were women and 92% were White. The ages ranged from 32 to 79 years, with

a mean of 54 years. More than 16% of the participants were older than age 65 years. Multiple types of cancer diagnoses and treatments were represented in the sample. Sixty percent of participants had breast cancer, and the others had seven other types of cancer. Sixty percent of participants had advanced disease. The great majority (84%) were married, and 77% were not working. The orientation to the TLC symptom collection system took 10 minutes or less for 89% of participants. All participants rated the system easy to learn.

Symptom Prevalence

Participants were asked to report on the prevalence (yes or no) of seven common symptoms during the previous 24 hours. All participants reported at least one symptom during the course of their chemotherapy cycle. The prevalence of the seven common symptoms is summarized in Table 2. Fatigue was the most common and was reported by 85% of participants and during half of the total calls. Fever was least common and was only reported by two participants. Fifty-six percent reported, at least once, that their symptoms interfered with their normal activities a great deal or totally. Eighteen (67%) of the 27 participants exceeded the preset symptom severity threshold at least one time and generated a TLC-Chemo Alert report that was faxed to their physician.

Participants who reported fatigue or nausea rated the severity and distress of these symptoms during the previous 24 hours (Table 3). Fatigue was not only more prevalent but also more severe and distressing than nausea. Participants who reported fatigue and nausea were asked several additional questions. For example, participants were asked how much time they had spent lying down, resting, or sleeping within the previous 24 hours. Seven participants (26%) reported at least once that they spent greater than 18 hours in this state.

Use of Telephone-Linked Care

Of 27 participants, four were excluded from subsequent analysis, because their data were incomplete due to

Table 2. Summary of Prevalence of Seven Symptoms Reported on TLC System (N = 27)

Symptom	Patients (No.)	%
Fatigue	23	85
Trouble sleeping	16	60
Nausea/vomiting	15	56
Feeling blue	13	48
Anxiety or nervousness	12	44
Sore mouth	12	44
Fever	2	7
Participants reporting 1 or more symptoms	27	100

friendly manner. Because it is inherently inexpensive to operate, it might be particularly attractive to healthcare service delivery organizations, which are increasingly under pressure to provide effective services at lower costs. Such a data collection method has potential applications in both cancer care and cancer research, including improved data collection in cancer clinical trials. The database generated by the system also could be linked to other clinical databases, thus further supporting clinical practice by providing a complete pattern of the symptom experience for every patient with cancer.

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